UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: December 10, 2014

SUBJECT: Oxalic Acid. New Use in Bee Hives to control Varroa mites. D424360

PC Code: 009601
Decision No.: 497398
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID No.: NA

DP Barcode: 424360
Registration No.: 91266-R
Regulatory Action: New Use
Case No.: NA
CAS No.: NA
40 CFR: NA

FROM: Michael S. Metzger, Chief
Risk Assessment Branch VII
Health Effects Division (7509P)

TO: Meredith Laws, Chief
Invertebrate-Vertebrate Branch 3
Registration Division (7505P)

The U.S. Department of Agriculture has requested a new use of oxalic acid dihydrate (91266-R, oxalic acid dihydrate 100 % w/w a.i.) to control Varroa mites in honey bee hives.

A Reregistration Eligibility Decision (RED) document for Oxalic acid was issued in 1992.

As part of a work share with the U.S. EPA, Canada's Pest Management Regulatory Agency (PMRA) completed an updated review of the toxicity data for oxalic acid, a dietary assessment, and an occupational assessment for the proposed use (Brian Belliveau, Ph.D., Head, Microbial and Biochemical Evaluation Section, 10/26/2009). HED concurs with the conclusions drawn by PMRA and reiterates them, in part, below.

Oxalic acid is ubiquitous in the environment being found naturally in many plants and vegetables, as well as in honey. Dietary exposure from the proposed use will be insignificant and indistinguishable from background levels of oxalic acid; the use should be considered a food use without the requirement of a tolerance. Labeled personal protective equipment (PPE) is sufficient to reduce worker exposures to insignificant levels presenting no risk concern. Therefore, HED has no objection to granting this registration.

Toxicity:

Toxicity data for oxalic acid are summarized in the attached review from PMRA (Toxicology Review, Brian Belliveau, Ph.D., Head, Microbial and Biochemical Evaluation Section, 10/26/2009).

Proposed Use

Oxalic acid may be applied using two different methods as described below.

SOLUTION METHOD:

NOTE: To completely dissolve Oxalic Acid Dihydrate, use warm syrup.

Dissolve 35 g of Oxalic Acid Dihydrate in 1 liter of 1:1 sugar: water (weight:volume). Smoke bees down from the top bars. With a syringe or an applicator, trickle 5 ml of this solution directly onto the bees in each occupied bee space in each brood box. The maximum dose is 50 ml per colony whether bees are in nucs, single, or multiple brood chambers. Under certain unfavorable conditions (e.g., weak colonies, unfavorable overwintering conditions), this application methods may cause some bee mortality or overwintering bee loss.

VAPORIZER METHOD:

Apply only to outdoor colonies with a restricted lower hive entrance. Seal all upper hive entrances and cracks with tape to avoid escape of Oxalic Acid vapor. Smoke bees up from the bottom board, Place 2.0 g Oxalic Acid Dihydrate powder into vaporizer. Follow the vaporizer manufacturer's directions for use. Insert the vaporizer apparatus through the bottom entrance. Apply heat until all Oxalic Acid has sublimated.

Dietary and Aggregate Exposure:

The following summary is taken from the PMRA dietary exposure review (Dietary Exposure Review, Brian Belliveau, Ph.D., Head, Microbial and Biochemical Evaluation Section, 10/26/2009). HED concurs with these conclusions [*information in brackets added by HED*]:

"Oxalic acid occurs naturally in honey with amounts varying with the type of flower pollen is collected from. The applicant is unable to provide a range of values of oxalic acid in Canadian Honey, but submitted information which suggests that European honey contains 1-800 mg/kg, depending on the botanical source of the pollen.

It is anticipated that the amount of oxalic acid present as a food residue after application of the end use product will not likely exceed the naturally occurring background concentration currently found in honey or vegetables (300-17,000 mg/kg for vegetables). It is also expected that a majority of available oxalate anion will bind with calcium (also naturally occurring in honey) on ingestion, resulting in a compound which is poorly absorbed by the gastro-intestinal tract (GI tract). Excretion of calcium oxalate in the faecal matter and urine of rodents was evidenced upon ingestion of oxalic acid in non-fasted animals. Less than 10

% of the administered dose was absorbed through the GI tract.

Distinguishing between endogenous and anthropogenic sources of oxalic acid and enforcing an MRL [*pesticide tolerance in the case of the U.S. registration*] is not possible. As such, promulgation of an MRL [*pesticide tolerance in the case of the U.S. registration*] will not be necessary."

HED concurs with this assessment. Since low level residues in honey are possible as a result of this use but are indistinguishable from endogenous sources, the use should be considered a food use, but a tolerance should not be required.

Since oxalic acid is ubiquitous in the environment and exposures from use in honey bee hives will be minimal, the contribution to aggregate risk from this use will be insignificant relative to the total exposure from other sources.

Worker Exposure:

The following label restrictions are included in the oxalic acid label (EPA Reg. No. 91266-R)

"Hazard avoidance: Do not breathe dust or fumes. Do not get in eyes, on skin, or on clothing. Wear protective clothing, eyewear, and respiratory protection as listed under "Personal Protective Equipment.." Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT:
Handlers and Applicators who apply product by the Solution Method must wear:
- Long-sleeved shirt and long pants
- Socks and shoes
- Waterproof gloves
- Protective eyewear (goggles or face shield)
- Half-face respirator with cartridge and/or particulate filter

Handlers and Applicators who apply product by the Vaporizer Method must wear:
- Long-sleeved shirt and long pants
- Socks and shoes
- Waterproof gloves
- Protective eyewear (goggles or face shield)
- Half-face respirator with cartridge and/or particulate filter

User Safety Requirements:
Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions are provided for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."

HED recommends that the label additionally specify that the respirator used when applying this product be used with an acid gas cartridge and a particulate filter.

HED has not selected endpoints related to use of oxalic acid in bee hives, or completed a quantitative risk assessment. However, based on the high level of personal protective equipment (PPE) required by the pesticide label, HED concludes that the label use restrictions will reduce worker exposures to oxalic acid to an insignificant level, unlikely to result in risks of concern.

Attachment: Toxicity Review from Canada's Pest Management Regulatory Agency

Health Canada / Santé Canada

Pest Management Regulatory Agency / Agence de réglementation de la lutte antiparasitaire

2720 promenade Riverside Drive
Ottawa, Ontario
K1A 0K9

Telephone/Téléphone: (613)736-3518
Fax/Télécopieur: (613)736-3505

October 26, 2009

Memorandum To/Note adressée à: Brian Belliveau, Ph.D.
Head, Microbial and Biochemical Evaluation Section
Health Evaluation Directorate, PMRA

From/De: Kevin Arnold
Senior Evaluation Officer, Microbial and Biochemical Evaluation Section
Health Evaluation Directorate, PMRA

Subject/Objet:

Sub. No(s):	1) 2008-4596 2) 2008-4584
Product Name:	1) Oxalic Acid Dihydrate 2) Oxalic Acid Varroa Mite Control Product
Active Ingredient:	Oxalic acid (OXL) / acaricide
Applicant:	Canadian Honey Council (HCA)

ACTION REQUESTED: **Level D, Category A.1.1 Submission Review (HED3) Toxicology**

Submission Information: The Canadian Honey Council has applied for the registration of a new source of the technical grade active ingredient (TGAI), Oxalic Acid Dihydrate (2008-4596), as well as the commercial registration of a new end-use product (EP), Oxalic Acid Varroa Mite Control Product (oxalic acid, 99.6 % w/w a.i.). The EP, a miticide, is proposed for use in the control of varroa mites on honey bees.

According to the U.S. EPA, oxalic acid is commonly used as an analytical reagent, in textile finishing, in metal, wood, or equipment cleaning, in bleaching straw and leather, in removing paint, varnish, rust, or ink stains, in dye manufacturing, in chemical synthesis, in the paper, ceramics, photographic, and rubber industries, *in vitro* as a blood specimen anticoagulant in veterinary medicine, *etc*.

Oxalic Acid Dihydrate and Oxalic Acid Varroa Mite Control Product (oxalic acid, 99.88 % w/w a.i.) were originally submitted for registration in 2005 as submissions 2005-0026 & 2005-0027 but were withdrawn by the applicant in 2006. An interim decision was made by the SMC and a letter notifying the Canadian Honey Council (Aucoin to Clay, October 5, 2005) that permission to use oxalic acid as an unregistered miticide in bee colonies would be granted if conditions and precautions determined by the PMRA were observed and followed. According to the Canadian Honey Council, concerns were raised by their members regarding the legality of using an unregistered pest control product in the colonies. The Canadian Honey Council has since reapproached the PMRA for full registration of the TGAI and associated EP.

Oxalic acid is not registered with the PMRA as a technical grade active ingredient but is present in a number of registered EPs as a formulant (list 3) since 2002. There are currently no active registrants using oxalic acid as active pesticide ingredient registered with the U.S. EPA. The only active submissions within the PMRA, involving oxalic acid as the TGAI, are those submitted by the Canadian Honey Council (2008-4596 & 2008-4584).

Review:

Technical Grade Active Ingredient

Acute Toxicity

Oxalic Acid Dihydrate has an oral LD_{50} of 375 mg/kg bw in female rats, and a dermal LD_{50} > 20,000 mg/kg bw in female rabbits. The inhalation LC_{50} was not included in the available literature, but the chemical nature of oxalic acid is such that one would expect irritation and mucosal burns to result from oxalic acid dust and/or fumes. The TGAI is classified as highly acutely toxic via the oral route and a low acute toxicity classification via the dermal route.

According to available literature, oxalic acid dihydrate is moderately irritating when applied to the skin and severely irritating to the eyes. The pH of oxalic acid dihydrate is 1.3, which suggests a corrosive compound. In light of the fact that detailed studies were not submitted by the applicant, classification of oxalic acid dihydrate with the skin or the eye will default to corrosive.

Although there was a lack of information with respect to oxalic acid's potential as a dermal sensitizer, the long history of use in a variety of processes and products, coupled with a general lack of medical reports regarding sensitization potential of oxalic acid, suggests that the TGAI is not a dermal sensitizer.

Table 1. Acute toxicity information for oxalic acid dihydrate (99.6 % w/w a.i.).

ACUTE STUDIES			
Oral (gavage)	Rat – Sprague-Dawley (5/sex)	LD_{50} (♀) 375 mg/kg bw LD_{50} (♂) 475 mg/kg bw **Highly acutely toxic.** (Based on the LD_{50} (♀) 375 mg/kg bw)	A NOAEL could not be determined from the available information. The principal display panel should include the statement **DANGER POISON**. **Fatal or Poisonous if swallowed** should be included on the secondary display panel.
Dermal	Rabbit – New Zealand white (3 females) Dose administered as a 5 % aqueous solution.	LD_{50} (♀) > 20,000 mg/kg bw **Low acute toxicity.**	A NOAEL could not be determined from the available information.
Inhalation	Information regarding acute inhalation was not available for evaluation. It is expected, however, that, due to the caustic nature of oxalic acid, inhaling dusts or fumes should be avoided. There are NIOSH and ACGIH adopted TLVs of 1 mg/m^3 (TWA) and 2 mg/m^3 (STEL).[a] The statements **Avoid inhaling/breathing dust or fumes** and **NIOSH approved mask should be worn** should be included on the secondary display panel.		
Eye Irritation	Rabbit Dose: 250 µg of oxalic acid for 24 hours.	Extreme Irritation when unrinsed after 24 hours. **Severly irritating.**	In another study, corneal injury was resolved within 6 days (30 second exposure to a 5 % solution). Since the pH of oxalic acid dihydrate is 1.3, eye irritation will be categorized as

			corrosive. The principal display panel should include the statement **DANGER – CORROSIVE TO EYES**. The secondary display panel should include **CORROSIVE to the eye** and **DO NOT get in eyes**.
Dermal Irritation	Rabbit Dose: 500 mg of oxalic acid for 24 hours.	**Moderately Irritating.**	The principal display panel should include the statement **DANGER – SKIN IRRITANT**. The secondary display panel should include **Corrosive to skin** and **DO NOT get on skin**.
Dermal Sensitization	Although there appears to be no available information regarding dermal sensitization, the long history of use suggests that oxalic acid is not a potential sensitizer.		

a - TLV - Threshold Limit Value; TWA – Time Weighted Average; STEL – Short-Term Exposure Limit; NIOSH – National Institute for Occupational Safety and Health; ACGIH – American Conference of Government Industrial Hygienists.

Short-term Toxicity

Young adult Long-Evans rats were administered oxalic acid in the diet at 0, 2.5, and 5.0 % (estimated to be 0, 1.98, and 5.3 g/kg bw/day in females; 0, 1.78, and 5.3 g/kg bw/day in males) for 70 days.

There was an statistically significant decrease in term body weight in both the 2.5 and 5.0 % dose groups ($p<0.001$ in males and females. The mortality rate for the 5.0 % dose group was 25 %, whereas the mortality rate for the 2.5 % group was < 10 %. There were no clinical effects apparent in the 2.5 % dose group, but pronounced effects were noted in the 5.0 % dose group, *i.e.*, emaciated, stunted, gaunt with arched backs.

Gross pathology results demonstrated a lack of body fat and a minimal amount of adipose tissue adherent to visceral and endocrine tissue, as well as kidneys which were discoloured, brownish with roughened crinulated surfaces, abnormal notching on the edges and small stones. All pathology findings were observed in male and female rats at 5.0 % oxalic acid. The majority of these findings are consistent with emancipated animals, resulting from a significant loss of body weight in the test animals and not necessarily due to the direct effects of oxalic acid. The kidney pathology may have been due to exposure

from oxalic acid, but insufficient data was available in the literature to verify these findings.

Additional short-term toxicity information was not available. It is expected that, due to the long history of use in a number of manufacturing processes and goods, exposure to oxalic acid is unlikely to result in short-term toxicological effects.

Prenatal Developmental Toxicity

Information with respect to prenatal developmental toxicity was not available. It is expected that, due to the long history of use in a number of manufacturing processes and goods, exposure to oxalic acid is unlikely to result in prenatal developmental toxicological effects.

Mutagenicity and Genotoxicity

Anhydrous oxalic acid (99 %), in water as a solvent, was tested for bacterial mutagenicity using the AMES assay, *i.e.*, *Salmonella typhimurium* strains TA1535, TA1537, TA98, and TA100. The doses tested were 0.0 - 6666.7 Φg/plate, with and without metabolic activation, *i.e.*, rat and hamster liver S-9, Aroclor 1254 induced. Positive controls were also tested concurrently. The positive control chemical 2-aminoanthracene was tested on all strains in the presence of rat and hamster S-9. 4-Nitro-o-phenylenediamine was tested on TA98 without S-9, 9-aminoacridine was tested on TA1537 without S-9, and sodium azide was tested on TA100 and TA1535 without S-9. The number of revertants was used as the endpoint and a positive result was determined to be a result of at least 2x the background count.

All other genotoxicity results were negative, with or without metabolic activation.

Additional information with respect to mutagenicity and genotoxicity was not available. It is expected that, due to the long history of use in a number of manufacturing processes and goods, exposure to oxalic acid is unlikely to result in mutagenic and/or genotoxic effects.

End Use Product

Acute Toxicity

The end use product is the same as the technical grade active ingredient, therefore, the acute toxicity of the EP will be identical to the TGAI.

The reader is referred to the acute toxicity section of the technical grade active ingredient of this evaluation report.

Label Recommendations:

Technical Grade Active Ingredient

Principal Display panel

Remove the following statements and pictographs:

OXALIC ACID

Varroa Mite Control Product

Agricultural

KEEP OUT OF REACH OF CHILDREN

POISON

CORROSIVE

Add the following statements and pictograph:

OXALIC ACID DIHYDRATE

FOR MANUFACTURING, FORMULATING OR REPACKAGING

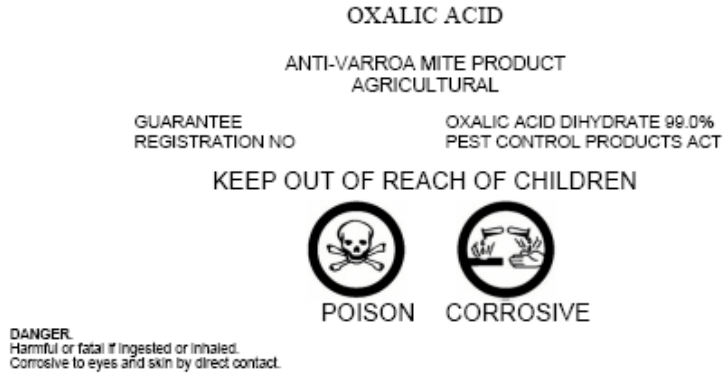
DANGER - POISON

DANGER – CORROSIVE TO EYES

DANGER – SKIN IRRITANT

Secondary Display Panel

Remove the following statements and pictographs from the beginning of the secondary display panel:



Remove the following statements from the **PRECAUTIONS** section:

> **Wear a full mask (or a half mask and goggles) fitted with organic acid filter and chemical resistant gloves when applying oxalic acid.**
>
> **Keep away from food, drink and bee feeds.**

Add the following statements to the **PRECAUTIONS** section:

> **PREVENT ACCESS BY UNAUTHORIZED PERSONNEL.**
>
> **Fatal or Poisonous if swallowed.**
>
> **Avoid inhaling/breathing dust or fumes.**
>
> **CORROSIVE to the eyes.**
> **DO NOT get in eyes.**
>
> **Corrosive to skin.**
> **DO NOT get on skin or clothing.**

Remove the following statements from the **FIRST AID** section:

> **Always carry large amount of clean water to wash skin and eyes immediately if contact with Oxalic Acid Dihydrate occurs.**
> **SKIN: Remove contaminated clothing immediately. Wash affected area with soap or mild detergent and large amounts of water. If chemical burn develops, cover area with a sterile, dry dressing and bandage securely. Contact a physician immediately.**
>
> **EYES: Wash eyes immediately with large amounts of water. Cover with sterile bandages. Contact a physician immediately.**
>
> **INGESTED. Do not induce vomiting. Drink large quantities of water or milk. If vomiting occurs, administer fluids repeatedly. Never give anything by mouth to an unconscious person. Contact a physician or Poison Control Center immediately.**

INHALED. Remove victim to a safe, uncontaminated area. Rest. Keep warm. If breathing is shallow, give oxygen. Get immediate medical attention.

Add the following statements to the **FIRST AID** section:

If swallowed	**Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.**
If on skin or clothing	**Take off contaminated clothing. Rinse skin immediately with plenty of water for 15–20 minutes. Call a poison control centre or doctor for treatment advice.**
If inhaled	**Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.**
If in eyes	**Hold eye open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.**

Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

Add the following section and associated statement to the secondary display panel:

TOXICOLOGICAL INFORMATION.

Treat symptomatically.

End Use Product

Principal Display Panel

Remove the following statements and pictographs:

OXALIC ACID

POISON

CORROSIVE

Add the following statements and pictograph:

OXALIC ACID DIHYDRATE

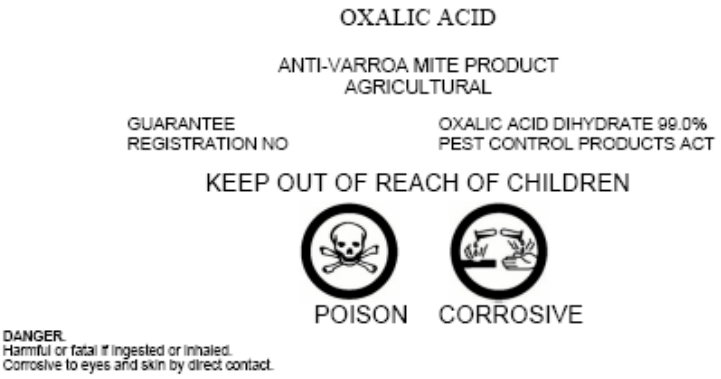
DANGER - POISON

DANGER – CORROSIVE TO EYES

DANGER – SKIN IRRITANT

Secondary Display Panel

Remove the following statements and pictographs from the beginning of the secondary display panel:



Add the following statements to the **PRECAUTIONS** section:

Fatal or Poisonous if swallowed.

Avoid inhaling/breathing dust or fumes.

CORROSIVE to the eyes.
DO NOT get in eyes.

Corrosive to skin.
DO NOT get on skin or clothing.

Remove the following statements from the **FIRST AID** section:

Always carry large amount of clean water to wash skin and eyes immediately if contact with Oxalic Acid Dihydrate occurs.
SKIN: Remove contaminated clothing immediately. Wash affected area with soap or mild detergent and large amounts of water. If chemical burn develops, cover area with a sterile, dry dressing and bandage securely. Contact a physician immediately.

EYES: Wash eyes immediately with large amounts of water. Cover with sterile bandages. Contact a physician immediately.

INGESTED. Do not induce vomiting. Drink large quantities of water or milk. If vomiting occurs, administer fluids repeatedly. Never give anything by mouth to an unconscious person. Contact a physician or Poison Control Center immediately.

INHALED. Remove victim to a safe, uncontaminated area. Rest. Keep warm. If breathing is shallow, give oxygen. Get immediate medical attention.

Add the following statements to the **FIRST AID** section:

If swallowed	**Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.**
If on skin or clothing	**Take off contaminated clothing. Rinse skin immediately with plenty of water for 15–20 minutes. Call a poison control centre or doctor for treatment advice.**
If inhaled	**Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.**
If in eyes	**Hold eye open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.**

Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

Add the following section and associated statement to the secondary display panel:

TOXICOLOGICAL INFORMATION:

Treat symptomatically.

Formulant Toxicology: There were no formulants of toxicological concern. See Appendix 1.

TGAI: (HED3) Toxicology Level D Passed.

EP: (HED3) Toxicology Level D Passed.

Reviewed by:

_____Date:_____
Kevin Arnold
Senior Evaluation Officer, Microbial and Biochemical Evaluation Section
Health Evaluation Directorate, PMRA

Peer Reviewed by:

_____Date:_____
Sathish Achuthan
Evaluation Officer, Microbial and Biochemical Evaluation Section
Health Evaluation Directorate, PMRA

Approved by:

_____Date:_____
Brian Belliveau, Ph.D.
Head, Microbial and Biochemical Evaluation Section
Health Evaluation Directorate, PMRA

REFERENCES

966154 CHEMINFO : Oxalic Acid. www.intox.org/databank/documents/chemical/oxalicac/cie358.htm Retrieved: August 27, 2004. 13pp. Published, DACO: 2.14.1,2.14.2,2.14.3,2.14.4, 2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.3.1,2.4,2.5,2.6,2.7,2.8,4.1,4.2.1,4.2.4,4.2.6,4.4.2,

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1669578 2008, Draft Label, DACO: 1.1.1

1810554 2004 TLVs and BEIs - Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices, DACO: 4.8

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1810564 M. Grant, 1962, Toxicology of the Eye, DACO: 4.8

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REFERENCES - CBI

1767370 DACO: 0.1.6003

Appendix 1: Product Specifications

Purpose	Acaricide
Formulation Name	Oxalic Acid Dihydrate Varroa Mite Control Product
Technical Active (%)	Oxalic Acid Dihydrate (99.6 %)
PCP / Appl. No.	2008-4584
Use Pattern	USC # 8 – Livestock For Food

Formulant Evaluation

Formulant Ingredient	CAS #	Purpose in Formulation	Percent by Weight	PMRA Formulant List
None.	N/A	N/A	N/A	N/A

PMRA List:
List 1: Contains formulants identified as being of significant concern with respect to their potential adverse effects on health and the environment, meeting defined criteria for carcinogenicity, neurotoxicity, chronic effects, adverse reproductive effects, ecological effects, Track 1 substances as defined under the Toxic Substances Management Policy (TSMP) and substances designated under the Montreal Protocol.

List 2: Contains formulants that are considered potentially toxic, based on either structural similarity to List 1 formulants or data suggestive of toxicity.

List 3: Contains formulants that do not meet the criteria of any of the other lists.

List 4A: Contains formulants that appear on the USEPA Minimum Risk Inerts List, which are generally regarded to be of minimal toxicological concern, as well as substances commonly consumed as foods.

List 4B: Includes formulants, some of which may be toxic, but for which there are sufficient data to reasonably conclude that the specific use pattern of the pest control product [as on specific use pattern listed in the United States Code of Federal Regulations, 40 CFR Protection of Environment, Subpart D 180.000(c)(d)(e)] will not adversely affect public health and the environment.

The IR-4 Project
Pest Management Solutions for
Specialty Crops and Minor Uses

IR-4 Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201 W
Princeton, NJ 08540
732.932.9575
fax: 609.514.2612
www.ir4.rutgers.edu

February 12, 2020

Federal Government Agency Exemption for Pesticide Registration Improvement Act (PRIA) fees

Nancy Fitz
Minor Use Team Leader
Document Processing Desk (REGFEE)
Office of Pesticide Programs – (7504P)
2777 Crystal Drive
Arlington, VA 22202

Dear Ms. Fitz:

RE: **Petition for the Exemption from the Requirement of a tolerance** and **label amendment**:
PRIA category: R150

Active Ingredient: Oxalic acid dihydrate, 91266-1
End Use Product: Oxalic acid dihydrate

USDA ARS, Bee Research Laboratory, 10300 Baltimore Ave, Bldg. 306, BARC-East, Beltsville, MD 20705, EPA Company Number 91266

IR-4 PR # 1065B

On behalf of USDA ARS, Bee Research Laboratory, 10300 Baltimore Ave, Bldg. 306, BARC-East, Beltsville, MD 20705, IR-4 is submitting a petition for the exemption from the requirement of a tolerance for the active ingredient: Oxalic acid dihydrate.

Also included in this submission is a label amendment to allow use of oxalic acid when honey supers are on the hive.

The Section 3 registration package associated with the active ingredient oxalic acid dihydrate is simultaneously being submitted by the IR-4 Program, Princeton, NJ as an electronic submission only using EPA's CDX Pesticide Submission Portal (PSP).

The USDA Agricultural Research Service is the primary research agency of the USDA. Documentation of USDA-ARS research authority can be found at https://www.ars.usda.gov/. The USDA ARS, Bee Research Laboratory company number is 91266. USDA ARS, Bee Research Laboratory is requesting an exemption from Pesticide Registration Improvement Act (PRIA) fees for the exemption from the requirement of a tolerance and label amendment for oxalic acid dihydrate.

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations and USDA-ARS.

Enclosed in this submission are the administrative volume, data volumes, Notice of Filing, Letter of Authorization, and the following registration forms:

- EPA Form 8570-1, Application for Pesticide for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-4, Confidential Statement of Formula for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-34, Certification with Respect to Citation of Data for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-35 Data Matrix (EPA copy) for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-35 Data Matrix (Public copy) for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-36, Summary of Physical/Chemical Properties for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-37, Self-Certification Statement for the Physical/Chemical Properties for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- Current Oxalic acid dihydrate label (EPA Reg. No. 91266-1)
- Proposed Amended Oxalic acid dihydrate label (EPA Reg. No. 91266-1)

Vol. #	Volume Title	PP No.
1	Petition for Exemption from the Requirement of a Tolerance for Oxalic Acid Dihydrate and Label Amendment	---
2	Oxalic Acid Dihydrate, Product Properties Test Guidelines and Residue Chemistry Test Guidelines	51016401
3	Oxalic Acid Dihydrate, Health Effects Test Guidelines	51016402
4	Oxalic Acid Dihydrate, Ecological Effects and Environmental Fate Test Guidelines	51016403

Yours very truly,
Interregional Research Project No. 4
Petitioner

William P. Barney
IR-4 Project, Rutgers University
500 College Road East, Suite 201W
Princeton, New Jersey 08540
Office: 732-932-9575 ext. 4603, Fax: 609-514-2612
barney@njaes.rutgers.edu

Copies: Elizabeth Hill; email: elizabeth.hill2@usda.gov (Uploaded letter, administrative, data volumes and submission documents)

Garland Waleko; email: garland.p.waleko@usda.gov (Uploaded letter, administrative, data volumes and submission documents)

IR-4 Regional Coordinators (Uploaded letter & administrative volume)

Michael Braverman, Dan Kunkel, Jerry Baron (IR-4, letter only)

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations and USDA-ARS.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 91266-1

2. EPA Product Manager:

3. Proposed Classification: [x] None [ ] Restricted

4. Company/Product (Name): Oxalic acid dihydrate

PM#:

5. Name and Address of Applicant *(Include ZIP Code)*

USDA ARS, Bee Research Laboratory, 10300 Baltimore Ave, Bldg. 306, BARC-East, Beltsville, MD 20705

[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [x] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Request exemption from the requirement of a tolerance and amend oxalic acid dihydrate label (91266-1) to add additional use. Includes Federal government fee exemption, FIFRA section 33(b)(7)(G) for ASR, a federal agency that is part of the larger USDA organization.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: [ ] Yes* [x] No

** Certification must be submitted*

Unit Packaging: [ ] Yes [x] No

If "Yes" Unit Packaging wgt. / No. per container

Water Soluble Packaging: [ ] Yes [x] No

If "Yes" Package wgt / No. per container

2. Type of Container: [ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____

3. Location of Net Contents Information: [ ] Label [x] Container

4. Size(s) Retail Container:

5. Location of Label Directions: [ ] On Label [x] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [x] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
William Barney	Coordinator, IR-4 Project	732-932-9575

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature ROBERT BACA — Digitally signed by ROBERT BACA Date: 2020.02.09 18:18:33 -05'00'

3. Title: Assist. Dir. Compliance & Envir. Coord.

4. Typed Name: Robert M. Baca

5. Date: Feb 9, 2020

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to **Director, Collection Strategies Division (2822T) U.S.Environmental Protection Agency,1200 Pennsylvania Ave, NW,Washington, DC20460.**

INSTRUCTIONS: This form is to be used all applications for new registration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-34)**.** [If not exempted by 40 CFR 152.81(b)(4)].
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Data Matrix.

Submission of Labeling -Labeling should first be submitted in the form of draft labeling with all applications. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 **x** 11 inch file**.** Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data -Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with new registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amendments actions, resubmissions, notifications, reregistrations, etc., Sections I**,** II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - The section must be completed, as applicable, for all registration actions.

1. **Company /Product Number -** Insert your company number, if one has been assigned by EPA. This number rnay have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager -**If known, fill in the name end PM number of the EPA Product Manager.
3. **Proposed Classification -**Specify the proposed classification of this product. For most products the classification would be “None”.
4. **Product Name -**Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant -**The name of the firm or parson and address shown in your application is the person or firm to whom the registration will be issued. If you are acting on behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in theUnited Statesmust have an authorized agent residing in theUnited Statesto act for them in all registration matters. The name rand complete mailing address of such an agent must accompany this application.
6. **Expedited Review -**FlFRA section 3 (c) 3 **(B)** provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II -This section must be completed for a11 applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. **The Explanation Section should be used for any additional information regarding Sections I and II.**

1. Subject of submission -Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for he submission, such as “the addition of a site, pest or crop (specify)”; “amend the Confidential Statement of Formula by…”; “reregistration submission”; “general label revision of direction for use”, `notification for…”. Attach a separate page if additional space is needed.

SECTION III - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging -**Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container**- Indicate type of container in which product will be marketed.
3. **Location of Net Contents -**Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container -**Specify the net contents of all retail containers for your product.
5. **Location of Use Directions -**Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product -**Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) -This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5.Self-explanatory
6. EPA Use Only

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
USDA ARS, 10300 Baltimore Ave, Bldg 306 BARC-East, Beltsville, MD 20705	91266-1
Active Ingredient(s) and/or representative test compound(s) Oxalic acid dihydrate	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food crop	Product Name Ocalic Acid Dihydrate

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
ROBERT BACA Digitally signed by ROBERT BACA Date: 2020.02.09 18:23:35 -05'00'	09 Feb 2020	Robert M. Baca, Assist. Dir. Compl.& Envir Coord.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

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BIOCHEMICAL DATA MATRIX

Date	EPA Reg No/File Symbol 91266-1	Page 1 of 5
Applicant's/Registrants Name and Address USDA ARS, 10300 Baltimore Ave, Bldg 306 BARC-East, Beltsville, MD 20705	Product Oxalic acid dihydrate	

Ingredient: Oxalic acid dihydrate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note Volume number
830.1550	Product Identify and Composition		PMRA	PER	footnote 1
830.1550	Product Identify and Composition	51016401	USDA ARS	OWN	
830.1600	Description of Starting Materials Used to Produce Product		PMRA	PER	footnote 2
830.1600	Description of Starting Materials Used to Produce Product	51016401	USDA ARS	OWN	
830.1620	Description of Production Process		PMRA	PER	footnote 3
830.1620	Description of Production Process		US EPA RED	OLD	
830.1620	Description of Production Process	51016401	USDA ARS	OWN	
830.1670	Description of the Formation of Impurities		PMRA	PER	footnote 4
830.1670	Description of the Formation of Impurities	51016401	USDA ARS	OWN	
830.1700	Preliminary Analysis		PMRA	PER	footnote 5
830.1700	Preliminary Analysis	51016401	USDA ARS	OWN	
830.1800	Enforcement Analytical Method		PMRA	PER	footnote 6
830.1800	Enforcement Analytical Method	51016401	USDA ARS	OWN	
830.6302	Color		PMRA	PER	footnote 7
830.6302	Color	51016401	USDA ARS	OWN	

Signature	Name and Title	Date
ROBERT BACA Digitally signed by ROBERT BACA Date: 2020.02.09 18:27:33 -05'00'	Robert M. Baca, Assistant Director, Compliance and Environmental Coordination	09 Feb 2020

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BIOCHEMICAL DATA MATRIX

Date	EPA Reg No/File Symbol 91266-1	Page 2 of 5
Applicant's/Registrants Name and Address USDA ARS, 10300 Baltimore Ave, Bldg 306 BARC-East, Beltsville, MD 20705	Product Oxalic acid dihydrate	

Ingredient: Oxalic acid dihydrate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note Volume number
830.6303	Physical State		PMRA	PER	footnote 8
830.6303	Physical State	51016401	USDA ARS	OWN	
830.6304	Odor		PMRA	PER	footnote 9
830.6304	Odor	51016401	USDA ARS	OWN	
830.6313	Stability		PMRA	PER	footnote 10
830.6313	Stability	51016401	USDA ARS	OWN	
830.6314	Oxidation/Reduction		PMRA	PER	footnote 11
830.6314	Oxidation/Reduction	51016401	USDA ARS	OWN	
830.6316	Explodability		PMRA	PER	footnote 12
830.6316	Explodability	51016401	USDA ARS	OWN	
830.6317	Storage Stability		PMRA	PER	footnote 13
830.6317	Storage Stability	51016401	USDA ARS	OWN	
830.7000	pH		PMRA	PER	footnote 14
830.7000	pH	51016401	USDA ARS	OWN	
830.7300	Density		PMRA	PER	footnote 15
830.7300	Density	51016401	USDA ARS	OWN	

Signature	Name and Title	Date
ROBERT BACA Digitally signed by ROBERT BACA Date: 2020.02.09 18:27:09 -05'00'	Robert M. Baca, Assistant Director, Compliance and Environmental Coordination	09 Feb 2020

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BIOCHEMICAL DATA MATRIX

Date	EPA Reg No/File Symbol 91266-1	Page 3 of 5
Applicant's/Registrants Name and Address USDA ARS, 10300 Baltimore Ave, Bldg 306 BARC-East, Beltsville, MD 20705	Product Oxalic acid dihydrate	

Ingredient: Oxalic acid dihydrate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note Volume number
860.1550	Proposed tolerance		USDA ARS	OWN	
860.1560	Reasonable ground to support tolerance		USDA ARS	OWN	
860.1300	Nature of the residue plants		PMRA	PER	footnote 16
860.1380	Storage stability		PMRA	PER	footnote 17
870.1100	Acute oral toxicity		PMRA	PER	footnote 18
870.1100	Acute oral toxicity	51016402	USDA ARS	OWN	
870.1200	Acute dermal toxicity		PMRA	PER	footnote 19
870.1200	Acute dermal toxicity	51016402	USDA ARS	OWN	
870.1300	Acute inhalation toxicity		PMRA	PER	footnote 20
870.1300	Acute inhalation toxicity	51016402	USDA ARS	OWN	
870.2400	Primary eye irritation		PMRA	PER	footnote 21
870.2400	Primary eye irritation	51016402	USDA ARS	OWN	
870.2600	Primary skin irritation		PMRA	PER	footnote 22
870.2600	Primary skin irritation	51016402	USDA ARS	OWN	
870.6200	Dermal sensitization		PMRA	PER	footnote 23
870.6200	Dermal sensitization	51016402	USDA ARS	OWN	
870.5100	Bacterial reverse mutation assay		PMRA	PER	footnote 24
870.5100	Bacterial reverse mutation assay	51016402	USDA ARS	OWN	
870.3700	Prenatal developmental toxicity		PMRA	PER	footnote 25

Signature	Name and Title	Date
ROBERT BACA Digitally signed by ROBERT BACA Date: 2020.02.09 18:26:45 -05'00'	Robert M. Baca, Assistant Director, Compliance and Environmental Coordination	09 Feb 2020

Form Approved OMB No. 2070-0060

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Washington, D.C. 20460

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BIOCHEMICAL DATA MATRIX

Date	EPA Reg No/File Symbol 91266-1	Page 4 of 5
Applicant's/Registrants Name and Address USDA ARS, 10300 Baltimore Ave, Bldg 306 BARC-East, Beltsville, MD 20705	Product Oxalic acid dihydrate	

Ingredient: Oxalic acid dihydrate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note Volume number
870.3700	Prenatal developmental toxicity	51016402	USDA ARS	OWN	
850.1010	Aquatic Invertebrate Acute Toxicity		US EPA RED	OLD	
850.1010	Aquatic Invertebrate Acute Toxicity	51016403	USDA ARS	OWN	
850.1025	Oyster acute toxicity test		US EPA RED	OLD	
850.1035	Mysid Acute Toxicity Test		US EPA RED	OLD	
850.1045	Penaeid Acute Toxicity Test		US EPA RED	OLD	
850.1055	Bivalve Acute Toxicity Test		US EPA RED	OLD	
850.1075	Freshwater and Saltwater Fish Acute Toxicity		US EPA RED	OLD	
850.1075	Freshwater and Saltwater Fish Acute Toxicity	51016403	USDA ARS	OWN	
850.1300	Daphnid Chronic Toxicity Test		US EPA RED	OLD	
850.1400	Fish Early Life Stage Toxicity Test		US EPA RED	OLD	
850.2100	Avian Acute Oral Toxicity		US EPA RED	OLD	
850.2100	Avian Acute Oral Toxicity	51016403	USDA ARS	OWN	
850.2200	Avian Dietary Toxicity Test		US EPA RED	OLD	
850.2300	Avian Reproduction Test		US EPA RED	OLD	
850.3020	Honey Bee Acute Contact Toxicity		US EPA RED	OLD	
850.3020	Honey Bee Acute Contact Toxicity	51016403	USDA ARS	OWN	

Signature	Name and Title	Date
ROBERT BACA Digitally signed by ROBERT BACA Date: 2020.02.09 18:26:15 -05'00'	Robert M. Baca, Assistant Director, Compliance and Environmental Coordination	09 Feb 2020

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

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BIOCHEMICAL DATA MATRIX

Date	EPA Reg No/File Symbol 91266-1	Page 5 of 5
Applicant's/Registrants Name and Address USDA ARS, 10300 Baltimore Ave, Bldg 306 BARC-East, Beltsville, MD 20705	Product Oxalic acid dihydrate	

Ingredient: Oxalic acid dihydrate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note Volume number
850.4100	Seedling Emergence and Seedling Growth		US EPA RED	OLD	
850.4100	Seedling Emergence and Seedling Growth	51016403	USDA ARS	OWN	
835.1220	Sediment and Soil Adsorption/Desorption		US EPA RED	OLD	
835.1220	Sediment and Soil Adsorption/Desorption	51016403	USDA ARS	OWN	
835.1230	Adsorption/Desorption (Batch Equilibrium)		US EPA RED	OLD	
835.1240	Leeching Studies		US EPA RED	OLD	
835.1240	Leeching Studies	51016403	USDA ARS	OWN	
835.2120	Hydrolysis		US EPA RED	OLD	
835.2120	Hydrolysis	51016403	USDA ARS	OWN	
835.2240	Photodegradation in Water		US EPA RED	OLD	
835.2240	Photodegradation in Water	51016403	USDA ARS	OWN	
835.2410	Photodegradation in Soil		US EPA RED	OLD	
835.2410	Photodegradation in Soil	51016403	USDA ARS	OWN	
835.4100	Aerobic Soil Metabolism		US EPA RED	OLD	
835.4100	Aerobic Soil Metabolism	51016403	USDA ARS	OWN	
835.4300	Aerobic Aquatic Metabolism		US EPA RED	OLD	
835.4300	Aerobic Aquatic Metabolism	51016403	USDA ARS	OWN	
835.6100	Terrestrial Field Dissipation		US EPA RED	OLD	
835.6100	Terrestrial Field Dissipation	51016403	USDA ARS	OWN	

Signature	Name and Title	Date
ROBERT BACA Digitally signed by ROBERT BACA Date: 2020.02.09 18:25:50 -05'00'	Robert M. Baca, Assistant Director, Compliance and Environmental Coordination	09 Feb 2020

NOTE: All the citations in this table were provided to EPA in a work share agreement with the Canadian Pest Management Regulatory Agency (PMRA)		
Footnote Number	**PMRA Identifier**	**Citation**
1	1658706	Statement of Product Specification Form dated 2008-10-16
	1767371	Statement of Product Specification Form dated 2009-06-22
2	NA	Manufacturing, Composition and Impurity Information, Section 2.11.2
3	966160	Manufacturing, Composition and Impurity Information, Section 2.11.3
4	1669581	Statement of Product Specification Form dated 2008-10-16
	1767370	Statement of Product Specification Form dated 2009-06-22
5	1263989	SOP # 455-094 for a general procedure for sodium hydroxide titration, FR Aldrich Sheboygan QC, 9/25/01
	1622413	Batch data
	1622414	Batch data
	1622415	Batch data

NOTE: All the citations in this table were provided to EPA in a work share agreement with the Canadian Pest Management Regulatory Agency (PMRA)		
Footnote Number	**PMRA Identifier**	**Citation**
	1622416	Batch data
	1622417	Batch data
6	1263989	SOP # 455-094 for a general procedure for sodium hydroxide titration, FR Aldrich Sheboygan QC, 9/25/01
7	966154	CHEMINFO: Oxalic acid, created by CCOHS
8	966154	CHEMINFO: Oxalic acid, created by CCOHS
9	966154	CHEMINFO: Oxalic acid, created by CCOHS
10	NA	Manufacturing, Composition and Impurity Information, Table 2
11	NA	Manufacturing, Composition and Impurity Information, Table 2
12	966154	CHEMINFO: Oxalic acid, created by CCOHS
13	NA	Manufacturing, Composition and Impurity Information

NOTE: All the citations in this table were provided to EPA in a work share agreement with the Canadian Pest Management Regulatory Agency (PMRA)		
Footnote Number	**PMRA Identifier**	**Citation**
14	1767371	Statement of Product Specification Form dated 2009-06-22
15	1767371	Statement of Product Specification Form dated 2009-06-22
16	966165	Oxalic acid residues in honey. Melliferae.V,lmkerei Fischermühle, 72348 Rosenfeld,Germany. 2pp. Published, DACO: 4.1,7.4
	966166	Determination of residues in honey after treatments with formic and oxalic acid under field conditions. Apidologie 33:399- 409. Published, DACO: 4.1,7.4
	1658756	Pharmacodynamics of Oxalic acid and treatment residues in honey. Instituto Nazionale di Apicoltura, Bologna, Italy. 4pp. Published, DACO: 7.1
	1658764	Oxalic Acid Residues in Honey. Melliferae.V., Imkerei Fischermuhle, Rosenfeld, Germany. 2pp. Published, DACO: 7.4
	1658765	Oxalic Acid Residues in Honey. Melliferae.V., Imkerei Fischermuhle, Rosenfeld, Germany. 2pp. Published, DACO: 7.4.1
	1658769	Determination of residues in honey after treatments with formic and oxalic acid under field conditions. Apidologie 33:399- 409. Published, DACO: 7.4.1,7.4.2,7.4.3,7.4.4,7.4.5

NOTE: All the citations in this table were provided to EPA in a work share agreement with the Canadian Pest Management Regulatory Agency (PMRA)		
Footnote Number	**PMRA Identifier**	**Citation**
	1658771	Investigations on the oxalic content of honey from oxalic acid treated and untreated bee colonies. Eur.Food Res.Technol.217:49-52. Published, DACO: 7.4.5
	1810547	C. Curtin et. al., 1955, The Metabolism of Ascorbic Acid-1-C and Oxalic Acid-C In the Rat, DACO: 4.5.9
17	1658763	Storage of Oxalic Acid Sucrose Solution. Swiss Bee Research Center, Liebefeld, Switzerland. 3pp. Published, DACO: 7.2.5,7.3
18	NA	Toxicology, Acute Toxicity, Table 1 (10/26/2009)
19	NA	Toxicology, Acute Toxicity, Table 1 (10/26/2009)
20	NA	Toxicology, Acute Toxicity, Table 1 (10/26/2009)
21	NA	Toxicology, Acute Toxicity, Table 1 (10/26/2009)
22	NA	Toxicology, Acute Toxicity, Table 1 (10/26/2009)
23	NA	Toxicology, Acute Toxicity, Table 1 (10/26/2009)
24	NA	Toxicology, Mutagenicity and Genotoxicity (10/26/2009)

NOTE: All the citations in this table were provided to EPA in a work share agreement with the Canadian Pest Management Regulatory Agency (PMRA)		
Footnote Number	**PMRA Identifier**	**Citation**
25	NA	Toxicology, Prenatal Developmental Toxicity (10/26/2009)
26	966169	Nanetti, A. et al., 2003, Oxalic Acid Treatments for Varroa Control (Review)., Apiacta 38:81-87, DACO: 12.5.8
	966170	2001, New Zealand Ministry Agriculture and Forestry, Oxalic Acid Registration Submission for Varroa Control. NZMAF. Wellington NZ pp 21., DACO: 12.5.8
	1658729 (966059)	Oxalic acid treatment by trickling: field against Varroa destructor:recommendations for use in Central Europe and under temperate conditions. Bee World 83(2):51- 60. Published, DACO: 12.7
	1658730	Oxalic Acid Treatments for Varroa Control(Review). Apiacta 38:81-87. Published, DACO: 12.7
	1658731	Oxalic Acid Registration Data Submission for Varroa Control. NZMAF. Wellington, NZ pp 21., DACO: 12.7
	1658732	European Legislation Governing the Authorization of Veterinary Medicinal Products with particular reference to the use of drugs for the control of honey bee diseases. Apiacta 38:156-168. Published., DACO: 12.7

NOTE: All the citations in this table were provided to EPA in a work share agreement with the Canadian Pest Management Regulatory Agency (PMRA)		
Footnote Number	**PMRA Identifier**	**Citation**
	1658757	Committee for Veterinary Medicinal Products: Oxalic Acid Summary Report. EMEA/MRL/8901/03-Final December 2003 pp5. Published., DACO: 7.2.1
	1658758	Enzymatische BioAnalytik Oxalic Acid UV Method for the determination of oxalic acid in foodstuffs and other materials. Cat No. 10 755 699 035. R-Biopharm Ag,Landwehrstr. 54 D-64293 Damstadt, 3pp. Published, DACO: 7.2.1
	1658766	evaluation de l acide oxalique et de l acide formique en traitement du Varroa destructor pendant la periode estivale. Centre de recherche en sciences animales de Deschambault, Quebec. 29 pp Published, DACO: 7.4.1
	1658767	Evaporation of Oxalic Acid A Safe Method for the User? Institute for Occupational and Social Medicine. University of Tubingen, Tubingen, Germany. 14pp. Published, DACO: 7.4.1
	1658768	Varroa control with oxalic acid: a new application. In Proceedings of European Working Group for Integrated Varroa Control, Bern, Switzerland, June 16, 2000. 6pp Published, DACO: 7.4.1
	1658770	Homologation d une methode de controle du varroa par traitement en aerosol dans la chambre d hivernage. Centre de recherche en sciences animales de Deschambault, Quebec. 41pp. Published., DACO: 7.4.1,7.4.5

NA: PMRA Identifier not available/not assigned

Print Form

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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SUMMARY OF THE PHYSICAL/CHEMICAL PROPERTIES (PR Notice 98-1)

1. PRODUCT NAME: Oxalic acid dihydrate		**2. Reg. No.** 91266-1
3. COMPANY NAME: USDA ARS, Bee Research Laboratory, 10300 Baltimore Ave, Bld		**4. SUBMISSION DATE:**
5. FIRST SUBMISSION [ ] **6. RESUBMISSION** [X]	**7. PESTICIDE TYPE:** biochemical	**10. REGISTRATION** [ ]
8. FORMULATED MANUFACTURING-USE PRODUCT [ ] **or 9. END-USE PRODUCT** [X]		**11. REREGISTRATION** [ ]
13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN):		**12. REREG CASE #**

14. GUIDELINE REFERENCE NO.(GRN)/TITLE	**15. VALUE or QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES**	**16. MRID or REPORT NO.**
Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)		
-6302 Color	colorless solid	
-6303 Physical State	solid	
-6304 Odor	odorless	
-6314 Oxidation/Reduction: Chemical Incompatibility	medium strong acid which reacts vigorously with strong bases.	
-6315 Flammability/Flame Extension	reacts violently with oxidants causing fire and explosion hazard	
-6316 Explodability	if reacted with silver may form explosive silver oxalate	
-6317 Storage Stability	stable when stored in cool, dry, well-ventilated area away from incompatible substances	
-6319 Miscibility	N/A	
-6320 Corrosion Characteristics	Not expected to be corrosive to packaging material	
-6321 Dielectric Breakdown Voltage	N/A	
-7000 pH	1.3	
-7100 Viscosity	N/A	
-7300 Density/Relative Density/ Bulk Density	0.977 g/cm3	

INSTRUCTIONS ON HOW TO COMPLETE THE SUMMARY FORM (PR NOTICE 98-1)

1, 3 to 6 & 8 to 13: Self-explanatory.

2: Cite Registration Number or File Symbol Number. Leave blank if unknown or cite company number followed by a hyphen and XXX.

7: State whether your product is an insecticide, herbicide, fungicide, rodenticide, plant growth regulator, etc.

14: OPPTS Test Guidelines, Series 830, Product Properties (EPA publication 712-C-96-310,8/96) supersedes the Pesticide Assessment Guidelines, Subdivision-D, Product Chemistry, Series 60 to 64, and serves as one guideline for national and international product chemistry data requirements for chemical pesticides. Consistent with the certification statement, applicants must conduct the studies in substantial conformity with the detailed procedures described in OPPTS Test Guidelines. Published procedures or modifications may be used but must be referenced. If the applicant/registrant is fulfilling product chemistry requirements for a biochemical or microbial pesticides, cite the requirements opposite the corresponding GRNs listed on the form for chemical pesticides.

15: Indicate the experimental value, its average deviation and, where applicable, the method used, e.g., GC, HPLC, DTA/DSC (differential thermal analysis/scanning colorimetry). Provide qualitative descriptions, where applicable, and references such as ASTM, CIPAC, OECD, Federal Register, CFR, CRC Publication, Official Journal of the European Communities, EPA's Guidelines, etc. Examples on how to report some of these properties are shown on Attachment 3. Non-applicable studies can be indicated by using the term "N/A or Not-Applicable" then citing a regulatory and/or scientific reason as per the footnotes to the Table in 40 CFR 158.190. Studies in progress can be indicated as such "I/P or In Progress." Values or qualitative description of referenced or shared studies should also be indicated on the Form. All boxes in the form must be completed with data summaries and appropriate terms if not applicable or in progress. Resubmissions can be completed using a new form citing the applicants's response to the specific data gap or deficiencies and filling the remaining boxes with "N/A or Not-Applicable" if previously submitted and found adequate or "Upgraded" if a submitted study was rejected and needed upgrading, then cite the date of preceding data submissions followed by a summary of the upgraded information. The Form is expandable to allow reporting the requirements for registration/reregistration on separate sheets identified by product's name and Reg. No./File Symbol or Company No. Please note that abbreviations may be used if explained by identifying the corresponding full terms as footnotes to the Form.

16: Indicate company Report number if the study was generated and retained by the applicant or MRID number (Master Record Identification Number) if the study was previously submitted and assigned a number by the EPA. Company report number should not exceed eighteen (18) characters. It will be used by the Agency to recall certain studies if needed. When received by the Agency, properly formatted data will be assigned MRID number(s).

Specific Instructions by Guideline Reference Number (GRN)

GRNs 830-6319, -6321, -7000, -7100 & -7300 should be conducted in compliance with OPPTS Test Guidelines Series 830 Product Properties, or reported at 25°C unless otherwise noted.

GRN 830-6302, -6303 & -6317: Report qualitative description where applicable as per PR Notice 92-5.

GRN's 830-6315, -7000 & -7300: Reported values on the form should be consistent with those given on the Confidential Statement of Formula (CSF).

GRN 830-6303: Provide a brief description, e.g., solid, granular, liquid, powder, aqueous solution, emulsion, volatile liquid, gas, etc.

GRN 830-6314: Not applicable if the product does not contain an oxidizing or reducing agent or functional group of significant reactivity. This requirement includes those substances which the product is likely to contact including the storage container and dispensers during handling and use, e.g., iron, aluminum.

GRN 830-6315 For organic liquids, provide flash point in degrees Celsius (with Fahrenheit in parentheses). For aerosols provide flame extension and/or flash back if applicable to the nearest centimeters (with inches in parentheses). For non-combustible liquids and solids state "Non-Applicable."

GRN 830-6316: Indicate method of determination and cite references, e.g., differential thermal analysis/scanning colorimetry (DTA/DSC), (sharp exotherm at 60 degrees Celsius), by shock or impact explodability, hammer test or by structural analog, contains several nitro groups as in picric acid.
GRN 830-6317: Should be conducted for a minimum of one year under ambient warehouse conditions using commercial containers. Report the type of containers used and any changes in product composition at intervals of three months to the end of the test period relative to that at the beginning of testing. Any physical changes at the end of the test period must also be reported. Data on the stability study for technical grade of active ingredients (GRN 830-6313) will not satisfy the requirements for the storage stability (GRN 830-6317) for qualifying products. An interim 30 days storage stability study can be included with the first submission requesting a conditional registration pending compliance with all the requirements.

GRN 830-6320: May be conducted simultaneously with GRN 830-6317. Indicate changes in the commercial packaging containers (fluorinated high density polyethylene, plastic film, polyethylene liners, steel, tin, or paper) over a minimum of one year in storage under warehouse conditions.

GRN 830-7100: Flow curves for non-Newtonian fluids on viscosity can be appended to the form.

GRN 830-7300: For solids or powders, provide the bulk density in units, e.g., g/cc or lb/ft^3 whichever is preferred. For liquids, provide the density in grams/ml or lbs/gal.

Form Approved OMB No. 2070-0060

Form Approved. OMB Nos. 2070-0060; 2070-0057; 2070-0107

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

SELF-CERTIFICATION STATEMENT FOR THE PHYSICAL/CHEMICAL PROPERTIES (PR NOTICE 98-1)

Product Name: Oxalic acid dihydrate

Reg. No./File Symbol No.
(if known) or Company No. 91266-1

SELF-CERTIFICATION STATEMENT:

I certify that the reported information on the "Summary Form" represents a true and accurate record of the test results of studies generated or owned by (Company Name): USDA ARS, Bee Res Lab, 10300 Baltimore Ave, Beltsville, MD 20705 and that the values of the properties reported are reliable. I further certify that such data were generated in substantial conformity with OPPTS Test Guideline Series 830 Product Properties, applicable to my product, and in effect at the time of submission.

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of section 12(a)(2)(N) of FIFRA without opportunity for hearing, if I have not submitted to EPA within thirty (30) days of receipt of a request by the Agency, or within a specified time agreed to by the Agency, test results of studies summarized in the "Summary Form."

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of sections 12(a)(2)(N), 12(a)(2)(Q), or 12(a)(2)(R) of FIFRA without opportunity for hearing, if I fail to provide to EPA within thirty (30) days of receipt of a notification of error, or within a specified time agreed to by the Agency, information that EPA determines is required to correct the error.

Type Applicant's Name: Robert M. Baca

Title: Assistant Director, Compliance & Envir. Coordinator, APHIS	Telephone No. 301-851-2292
Applicant's Signature: ROBERT BACA Digitally signed by ROBERT BACA Date: 2020.02.09 18:37:09 -05'00'	Date: 09 Feb 2020

EPA Form 8570-37 (12-2003)

USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

February 12, 2020

Federal Government Agency Exemption for Pesticide Registration Improvement Act (PRIA) fees

Nancy Fitz
Minor Use Team Leader
Document Processing Desk (REGFEE)
Office of Pesticide Programs – (7504P)
2777 Crystal Drive
Arlington, VA 22202

Dear Ms. Fitz:

RE: **Petition for the Exemption from the Requirement of a tolerance** and **label amendment**:
PRIA category: R150

Active Ingredient: Oxalic acid dihydrate, 91266-1
End Use Product: Oxalic acid dihydrate

USDA ARS, Bee Research Laboratory, 10300 Baltimore Ave, Bldg. 306, BARC-East, Beltsville, MD 20705, EPA Company Number 91266

IR-4 PR # 1065B

The USDA ARS, Bee Research Laboratory, 10300 Baltimore Ave, Bldg. 306, BARC-East, Beltsville, MD 20705 is submitting a petition for the exemption from the requirement of a tolerance for the active ingredient: Oxalic acid dihydrate.

Also included in this submission is a label amendment to allow use of oxalic acid dihydrate when honey supers are on the hive.

The Section 3 registration package associated with the active ingredient oxalic acid dihydrate is simultaneously being submitted by the IR-4 Program, Princeton, NJ as an electronic submission only using EPA's CDX Pesticide Submission Portal (PSP).

The USDA Agricultural Research Service is the primary research agency of the USDA. Documentation of USDA-ARS research authority can be found at https://www.ars.usda.gov/. The USDA ARS, Bee Research Laboratory company number is 91266. USDA ARS, Bee Research Laboratory is requesting an exemption from Pesticide Registration Improvement Act (PRIA) fees for the exemption from the requirement of a tolerance and label amendment for oxalic acid dihydrate.

Enclosed in this submission are the administrative volume, data volumes, Notice of Filing, Letter of Authorization, and the following registration forms:

- EPA Form 8570-1, Application for Pesticide for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-4, Confidential Statement of Formula for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-34, Certification with Respect to Citation of Data for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-35 Data Matrix (EPA copy) for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-35 Data Matrix (Public copy) for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-36, Summary of Physical/Chemical Properties for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- EPA Form 8570-37, Self-Certification Statement for the Physical/Chemical Properties for Oxalic acid dihydrate (EPA Reg. No. 91266-1)
- Current Oxalic acid dihydrate label (EPA Reg. No. 91266-1)
- Proposed Amended Oxalic acid dihydrate label (EPA Reg. No. 91266-1)

Vol. #	Volume Title	PP No.
1	Petition for Exemption from the Requirement of a Tolerance for Oxalic Acid Dihydrate and Label Amendment	---
2	Oxalic Acid Dihydrate, Product Properties Test Guidelines and Residue Chemistry Test Guidelines	51016401
3	Oxalic Acid Dihydrate, Health Effects Test Guidelines	51016402
4	Oxalic Acid Dihydrate, Ecological Effects and Environmental Fate Test Guidelines	51016403

Yours very truly,
Petitioner

ROBERT BACA Digitally signed by ROBERT BACA
Date: 2020.02.12 11:34:09 -05'00'

Robert M. Baca, Assistant Director
Compliance and Environmental Coordination
Plant Protection and Quarantine (PPQ) APHIS
(301) 851-2292, Office Phone
robert.m.baca@aphis.usda.gov

Copies: Garland Waleko; email: garland.p.waleko@usda.gov (Uploaded letter, administrative, data volumes and submission documents)
IR-4 Regional Coordinators (Uploaded letter & administrative volume)
Bill Barney, Michael Braverman, Dan Kunkel, Jerry Baron (IR-4, letter only)